



HIGH VOLUME EVACUATION HOSE KIT

PRODUCT OVERVIEW

ErgoMedi's High Volume Evacuation (HVE) Hose Kit is a dental high-volume evacuation set of components to assist practitioners with the evacuation of fluid, splatter, and aerosol, especially meant for use together with the ErgoFinger® HVE. The HVE Hose Kit contains a lightweight hose together with an autoclavable ErgoFinger® HVE Tailpiece and an autoclavable ErgoFinger® HVE 2-IN-1 Adapter selected to make the use of the evacuation device more comfortable and ergonomic by reducing the overall weight for the operator's hand and fingers.

The HVE Hose Kit is meant for clinical use by dental professionals.

The HVE Hose Kit is meant to be attached with its ErgoFinger® HVE 2-IN-1 Adapter to the dental unit's existing HVE valve for the evacuation of fluid, debris, secretion, amalgam, and dentine generated during general dentistry, restorative, and hygiene procedures.

CONTRAINDICATIONS

There are no known contraindications.

Risk of allergic reactions cannot be excluded for those predisposed to allergies.

CAUTIONS

Before using this product, carefully read and follow all instructions and save them for future reference. Observe all precautions and warnings.

Inspect the device before each use for worn, loose, or damaged parts. Do not attempt to use the product unless it is properly installed. Replace any damaged parts, as necessary.

Do not attempt to use this product for any other purpose than indicated.

Improper use: any other usage or usage beyond this scope is deemed to be improper. The manufacturer(s) of the items mentioned in this document accepts no liability for damages resulting from improper use. In these cases the user/operator will bear the sole risk and responsibility. Do not evacuate any liquids and solid materials that are unsuitable for a dental evacuation system.

The product should be kept at room temperature with controlled humidity.

USA: USA FEDERAL LAW RESTRICTS THIS PRODUCT TO SALE BY OR ON THE ORDER OF A DENTIST OR A DENTAL HYGIENIST.

WARNINGS

Never install the ErgoFinger® HVE Hose Kit while the HVE system is operating.

It is the responsibility of the Healthcare Professional to determine the appropriate uses of this product and to understand the health of each patient, the dental procedures being undertaken, applicable industry and governmental agency recommendations for infection control in dental healthcare settings, requirements and regulations for safe practice of dentistry, and these instructions for use in their entirety.

Make sure to wear protective equipment when working (e.g. impermeable gloves, protective goggles and mouth and nose protection).

Clean and disinfect the evacuation hose, the ErgoFinger® HVE Tailpiece and the ErgoFinger® HVE 2-IN-1 adapter before working on the unit.

Disposal of the product must be in accordance with local laws and regulations.

Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical products, as well as with any specification for dental practices and clinics.

Comply with the specifications when selecting the cleaning and disinfectant agents to be used.

Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.

Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.

Do not use any rinse aid (danger of toxic residue on the components).

Only use freshly produced solutions.

Only use distilled or deionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).

Only aspirate clean water or suitable enzymatic evacuation cleaner.

Use clean, dry, oil and particle-free compressed air.

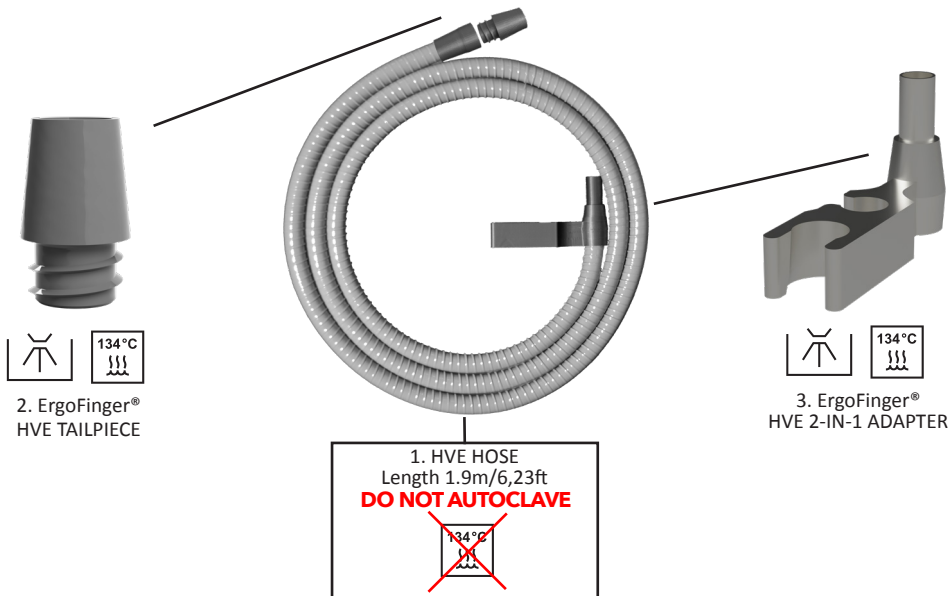
Do not exceed autoclave temperatures of 134°C (273°F) when sterilizing the tailpiece or the 2-IN-1 Adapter.

Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam sterilizer) to regular maintenance and inspections.

USA: Concerning the maintenance of the HVE Hose Kit, always follow the Guidelines for Infection Control in Dental Health-Care Settings (<https://www.cdc.gov/>) and use only FDA-cleared sterilant/high-level disinfectants and EPA-registered disinfectants.

COMPONENTS

The HVE Hose Kit is composed of a flexible HVE Hose with a connector (1), an autoclavable ErgoFinger® HVE Tailpiece (2) and an autoclavable ErgoFinger® HVE 2-IN-1 Adapter (3) for connecting to the existing HVE Valve of the dental unit.



ASSEMBLY AND INSTALLATION TO THE EXISTING HVE VALVE OF YOUR DENTAL UNIT

Start by shutting the central vacuum off at the main switch: you should never install the HVE Hose Kit while the HVE system is operating.

Connect the HVE Hose and the ErgoFinger® HVE Tailpiece part to the connector. Rotate it firmly into the connector. **DO NOT DISASSEMBLE THE CONNECTOR.**

Connect the wide part of the ErgoFinger® 2-IN-1 HVE Adapter into the HVE Hose. Rotate it firmly into the HVE hose.

Place the HVE Hose into the 2-IN-1 Adapter's hose holder. Press firmly inside to create a tight fit.

Place the HVE Tailpiece into the 2-IN-1 Adapters holder and adjust the ErgoFinger® HVE Hose to the desired position if needed.

Connect the 2-IN-1 Adapter's narrow part into the existing HVE Valve of your dental unit. Press firmly inside to create a tight seal.

Ensure the evacuation system is turned on before start of use.

REMEMBER TO CLOSE THE HVE VALVE FROM THE LEVER WHEN NOT USING THE ERGOFINGER®

INSTRUCTIONS FOR USE

The HVE Hose Kit is designed for use together with the ErgoFinger®.

After installing the pre-assembled HVE Hose Kit to the existing HVE Valve of your dental unit and before starting to use it together with the ErgoFinger®, ensure the evacuation system is turned on. Refer to the manufacturer's instructions for use. Depending on the dental units' HVE valve, do not forget to switch the lever from off to on.

Make sure that the ErgoFinger® is assembled correctly, as instructed in the separate dedicated manual. The ErgoFinger's tubing and the finger cup must have been joined in advance by the clinician. This is achieved by simultaneously rotating and pushing the transparent tubing into the finger cup's connector until the tubing is fully and firmly attached. Check visually that the parts of the ErgoFinger® are connected firmly and that the product is free from sharp edges or burrs.

Insert the tubing of the ErgoFinger® deep into the HVE Valve/Tailpiece, applying a rotational movement if needed. To ensure that the evacuation system is ready for use, you must aspirate a large glass of clear water through the pre-assembled hose kit before attaching the ErgoFinger®. Ensure the HVE Valve/Tailpiece has been disinfected and steam-sterilized before use. Additionally, the Valve/Tailpiece must be disinfected between patients, too, to prevent patient cross-contamination. Please follow the detailed infection control procedures described in the following chapter.

INFECTION CONTROL PROCEDURES

Before starting, at the beginning of the day:

Turn on the evacuation and air compressor systems, then switch on as well the master water. **To ensure that the evacuation system is ready for use, you must aspirate a large glass of clear water through the assembled evacuation hose and valve before starting.** Ensure the HVE Valve/Tailpiece has been disinfected and steam-sterilized before use. Additionally, the Valve/Tailpiece must be disinfected between patients, too, to prevent patient cross-contamination.

After completing each treatment:

Aspirate a large glass of clear water through the assembled HVE Hose and Valve/Tailpiece after each patient is treated. The HVE Hose, Valve, and Tailpiece must be sprayed or wiped with a suitable disinfecting solution after each treatment, between one patient and the next.

INFECTION CONTROL PROCEDURES

At the end of the day:

Follow the steps to comply with all national directives, standards, and specifications for the cleaning, disinfection, and sterilization of medical products, as well as with any specification for dental practices and clinics. Typically you would first disinfect the HVE Hose, Valve/Tailpiece, and the 2-IN-1 Adapter with a suitable spray or wiper disinfectant. Then, pre-clean by aspirating 1 liter (33 US FL oz) of clear water through the assembled HVE Hose Kit, followed by aspirating a suitable disinfectant/cleaning agent into the evacuation system. At this point, switch evacuation off by turning the lever, which is part of the valve, from the open to the closed position, and turn off the whole evacuation unit.

Next, remove the HVE Valve or Tailpiece and the 2-IN-1 Adapter from the Hose, and proceed with the parts' disinfection using automated cleaning equipment (ultrasonic cleaner or washer-disinfector). After the disinfection, autoclave them at 134°C (273°F), 2.1 bar, 3min. Control that the parts are thoroughly sterilized, as confirmed by the chemical indicator/test strip.

INFECTION CONTROL PROCEDURES

On a weekly basis:

It is recommended to have at least double the set of ErgoFinger® HVE Tailpieces and ErgoFinger® HVE 2-IN-1 Adapters, to ensure a pair is always readily disinfected and sterilized in case of sudden need.

On a monthly basis:

Check the condition of the hose. It is recommended to change the hose to a new one regularly. The time range for changing the hose to a new one varies **from 6 to 12 months**, depending on the dental office treatments’ frequency and quantity. In any case change the hose at least once a year.

Visit [ergofinger.com/pages/videos](https://www.ergofinger.com/pages/videos) for clear instructional videos on how to use and install the ErgoFinger® HVE Hose Kit and proper infection control procedures.

Disinfection and Sterilization:

Disinfection and sterilization are to be carried out in accordance with all national directives, standards, and specifications for the disinfection and sterilization of medical products, under the sole responsibility of the operator. The typical procedures that are simplistically described below are derived from the industry’s standard practices, following the indications for reprocessing appearing in the standard EN ISO 17664. The manufacturer has verified such procedures as suitable for ErgoFinger® HVE Tailpiece, for HVE Hose and The ErgoFinger® HVE 2-IN-1 Adapter.

Method	Temperature	Exposure / Dry Time
Steam / Pre-vacuum	134°C (273°F)	3 Minutes Exposure / 20 Minute Dry

Table 1: Recommended settings for autoclave

INAPPROPRIATE USE












When using the HVE Hose Kit correctly, one should never feel any pain or discomfort. If you are feeling pain or discomfort of any kind associated with using the HVE Hose Kit, stop using it immediately and check that your method of use is correct. Contact ErgoMedi Ltd. for additional instructions if needed. Do not continue to use the product until you’re sure that your method of use is appropriate.

PATENTS AND TRADEMARK

The ErgoFinger® is protected by the following patents:
Finland Pat. No.123608, US Pat. No. US 9,486,563 B2.
A Full list of all other patents can be found at [ergofinger.com/pages/patents](https://www.ergofinger.com/pages/patents)
ErgoFinger® is a Trademark of ErgoMedi LTD., a company having US Registration Number of 6010032 and International registration number of 1414527

The HVE Hose Kit is assembled and distributed by:

ErgoMedi Ltd., Linnoitustie 4A, 02600 Espoo, Finland
Phone: +358 40 8548 487
CUSTOMER SUPPORT AND FEEDBACK: support@ergofinger.com

SYMBOL	DEFINITION
	Lot Number
	Use By Date
	Manufactured On Date
	Manufactured By
	Do Not Use If Package Is Damaged
	Consult Instructions For Use
	Thermodisinfection at 93°C (197°F).
	Sterilization only in the autoclave at 134°C (275°F), 2.1 bar, 3min.
	Keep Dry
	Device is provided non-sterile
	Temperature Limit

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